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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,691	02/06/2007	Indranil Nandi	33422-US-PCT	3572
72554	7590	01/03/2011	EXAMINER	
SANDOZ INC 506 CARNEGIE CENTER PRINCETON, NJ 08540			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1617	
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			01/03/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/575,691

**Applicant(s)**

NANDI ET AL.

**Examiner**

Carlos A. Azpuru

**Art Unit**

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-129 is/are rejected.
- 7) ☒ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date 06082006
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Receipt is acknowledged of the information disclosure statement filed  
06/08/2006.

#### ***Election/Restrictions***

After review of applicant's arguments, the election/restriction is hereby  
withdrawn.

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-42 of copending Application No. 10/768,562 (US'562). Although the conflicting claims are not identical, they are not patentably distinct from each other because '562 an antibiotic composition comprising 1) a core comprising clarithromycin, (2) an inner coating comprising a cellulose polymer which is not an enteric coating polymer, and (3) an outer coating comprising at least one enteric coating polymer (claim 1). The cellulose polymers are listed at claims 5 and 6. Particle size is set out in claim 2 as between about 200  $\mu$ m to about 500  $\mu$ m. Plasticizers are listed at claims 7-9. Enteric coating polymers are found at claims 10-12. Oral suspensions are set out at claims 19-24. As such those of ordinary skill would have expected similar therapeutic results from the instantly claimed composition and from the instantly claimed composition manufactured from the instantly claimed method. As such, the claims of the instant invention would

have been obvious to one of ordinary skill in the art at the time of invention given the claims of copending US'562.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Claim Objections***

Claim 17 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 17 fails to further limit the method of producing the particle in that an oral composition as set out in claim 15 is manufactured for oral administration. Further, this step does not further limit the method of making. Correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Itoh et al (US Patent No. 6,221,402).

Itoh et al disclose a taste masking composition comprising a (1) core, (2) inner coating layer, and (3) outer coating (see Abstract). The core particles disclosed by Itoh et al have an average particle diameter between 80 and 400 microns (column 3, lines 37-45). According to Itoh et al, antibiotics such as erythromycin may be used as an active agent in the composition (col. 2, lines 61- col. 3, line 12) and may be present in a range between 20-40% by weight (col. 3, lines 46-58). The inner coating a core may comprise hydroxymethylpropyl cellulose (tables 1(a), 1(b), 1(c) and col. 6, lines 36-37). The outer cors may comprise Eudragit E100 (col. 7, lines 1-11 and Tables 1(a), 1(b), and 1(c)). magnesium stearate is used a s plasticizer in both the inner and outer coatings (see Table 1(a)). Further, while applicant's claims read on an inner coating consisting essentially of at least one cellulose polymer which is not an enteric coating polymer, hydroxymethylpropyl cellulose meets the limitation of "at least one which us not an enteric coating polymer". The existence of enteric coating polymers such as Eudragit NE 30 D in this inner coating does not change the fact that "at least one cellulose polymer is not an enteric coating polymer". The method of making is set out at col. 4, lines 64-67 and col. 5, lines 1-67. The core is provided with an addition of water (solvent), which is granulated, dried and coated. Excipients such as masking agents, lubricants and, binders are disclosed. A granulator (chopper) is used. As such, this limitation is fully met. The instant claims are anticipated by Itoh et al.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-5, 8, 9, 10, 12-16, 18 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Holt et al (US Patent 6,740,341).

Holt et al disclose a taste masking formulation comprising a core containing a drug and a taste masking layer (see Abstract; col. 2, lines 15-37). A core is found in col. 2, line 27; and Figure 1(11)). Antibiotics are listed among the drugs which need taste masking as shown at col. 3, line 64). The enteric layer may be aminoalkyl methacrylate copolymer (see col. 6, lines 40-41). The coated particle size range may be up to 850 microns (col. 7, lines 19-24). The method of production includes providing a core, with an addition of water (solvent), which is granulated, dried and coated (see Col. 5, lines 41-67 and col. 6, lines 1-9 and Examples 1-2). Excipients are disclosed at col. 5, lines 18-27. The instant claims are anticipated by Holt et al.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Itoh et al (as cited above).

The full disclosure of Itoh et al is set out above. A granulator is included in the method of forming the particles as setout therein. However, the rpm of the device is set out with a maximum of 200 rpm. However, those of ordinary skill would have known to modify their device in speed with a reasonable expectation of similar particulate products. There is not suggestion that the difference in speed of the device would produce different particles. Without such an expectation, it would have been within the skill of the ordinary practitioner to vary the speed of the device with a reasonable expectation of similar production of particles. as such, the instantly claimed method using an rpm of 100 would have been obvious to one of ordinary skill in the art at the time of invention.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fereydoun G. Sajjadi can be reached on (571) 272-3311. The fax phone



number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/  
Primary Examiner, Art Unit 1617

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